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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,796	07/28/2000	Krishan L. Taneja	BP9806US-CP2	3581

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Applied Biosystems
35 Wiggins Avenue
BEDFORD, MA 01730

EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,796

Applicant(s)

TANEJA, KRISHAN L.

Examiner

Jehanne S. Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,13-21,24-33,35-43 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,13-15,21,29-33 and 35-43 is/are rejected.
- 7) ☒ Claim(s) 1,4-10,13-15,21,29-33,35-43 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/04 1/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to the amendment filed 9/8/2004. Currently, claims 1, 4-10, 13-21, 24-33, 35-43, and 45 are pending in the instant application. Claims 16-20 and 24-28, as well as SEQ ID NOS 1-9 and 18-159 are withdrawn from consideration at this time as being drawn to non elected invention(s). Claims 1, 4-10, 13-15, 21, 29-33, 35-43 and 45, directed to chromosome Y probes (SEQ ID NOS 10-16), are currently under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following objections and 35 USC 112, 2nd paragraph rejections are newly applied, and constitute the complete set being presently applied to the instant application. While most are necessitated by amendment, a few were inadvertently omitted by the examiner in the previous office action. Accordingly, this action is NON-FINAL.

Information Disclosure Statement

2. The information disclosure statement filed 1/5/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a reference was not provided. A different reference listing the same first author was provided, but it did not reflect the citation listed in the IDS. This reference has been lined through by the examiner (see IDS enclosed with this office action) and was not considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

3. Claims 38 and 43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are directed to method steps and do not further limit the kit of claim 36 with any products or compositions.
4. Claims 1, 4-9, and 45 are objected to. These claims would be in condition for allowance except that they continue to recite non elected subject matter.
5. Claims 10, 13-15, 21, 29-33, 35-43, and 45 are objected to as they continue to recite non elected subject matter.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10, 13-15, 21, 29-33, and 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 10 and 35: Amended claim 10 recites “ A probe set comprising PNA probes...”, without reciting any minimum number of probes. Consequently, the recitation of “the one or more PNA probes” (found in both claims 10 and 35) lacks sufficient antecedent basis. It is unclear if this is meant to refer to a set of “one or more PNA probes”. However, with the amendment to the preamble of claim 10, it is also unclear if the probe set can contain only 2 probes because of the further recitation of “wherein: the one or more PNA probes of the set

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specific for detecting chromosome X comprise a probing nucleobase selected from the group consisting of... the one or more PNA probes of the set specific for detecting human chromosome Y comprise a probing nucleobase selected from the group consisting of ...the one or more PNA probes of the set specific for chromosome 1 comprise a probing nucleobase selected from the group consisting of...”. That is, it is unclear if the set must comprise at least one probe for each of the recited chromosomes, or applicant intends that the set comprise only a minimum of 2 probes and the recitation of each chromosome is meant in the alternative. Clarification is required because it is unclear how many probes are in the set. While an open ended upper length limit on number of probes is not problematic in this case, the minimum number of probes in the set is unclear. For instance, it is unclear if the instantly claimed set is drawn to “one or more PNA probes” or a minimum of 13 PNA probes (at least one for each chromosome listed in the claim). It is noted that the same applies to claim 35. In claim 35, it is unclear if the set minimally comprises 2 or 4 PNA probes.

B) Claim 21: In claim 21, the recitation of “the sample” in section a) now lacks antecedent basis due to the amendment to claim 21 to remove the term “sample” from the preamble.

C) Claim 36: The recitation of “the assay” in section b) lacks antecedent basis.

D) Claims 38 and 43 recite method steps but are dependent on a kit. Consequently, it is not clear if the claims were meant to add further components to the kit or not. Neither claim further limits the kit of claim 36 with any products or compositions.

Conclusion

8. No claims are presently in condition for allowance. It is noted that claims 10 and 35, drawn to sets of PNA probes, have been rejected under 35 USC 112/2nd paragraph because it is unclear how many probes, minimally, are in the set. Accordingly, these claims have also been objected to because they appear to recite non elected subject matter. PNA probes comprising a probing nucleobase sequence comprising each of SEQ ID NOS 10-16, respectively, have been searched and found to be free of the prior art. Accordingly, any claim drawn to a set of probes that contains at least one PNA probe comprising a probing nucleobase sequence selected from the group consisting of SEQ ID NOS 10-16, would also be free of the prior art. If applicant intends that each set contain at least 1 probe from each chromosome, as listed, these claims would no longer be objected to and would be allowable once 112/2nd paragraph issues were resolved, because each set would minimally comprise at least one PNA probe comprising a probing nucleobase sequence selected from the group consisting of SEQ ID NOS 10-16.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton

Primary Examiner

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4/25/05